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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: CFN 1122173

Public Health Service

M 3390

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

February 2, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Anthony F. Figaretti, Owner
Figaretti's Manufacturing and Distributing
227 Peters Run Road
Wheeling, West Virginia 26003

Dear Mr. Figaretti:

An inspection of your acidified low-acid food processing plant was conducted by an investigator with the Food and Drug Administration (FDA) on January 5, 2000. At the conclusion of the inspection, you were presented with a Form FDA 483 listing serious deviations from Title 21, Code of Federal Regulations (21 CFR), Parts 110 and 114. These sections cover the Good Manufacturing Practices for food processing and acidified foods, respectively. By virtue of these deficiencies, the products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigator found:

1. You have not assured that instruments and controls used for measuring the weights of acidifying ingredients and measurement of pH are accurate and adequately maintained. For example, you failed to calibrate the scale used to measure the citric acid ingredient added to your products. Additionally, you failed to calibrate the pH meter prior to each day's use, and the calibration buffers used were past their expiration date. [21 CFR 110.40(f) and 114.90(a)(4)]
2. You have not assured that tests and container examinations are conducted and documented to assure that the container protects food from leakage or contamination. For example, you failed to conduct or document glass jar seal integrity testing (pull-up test) on each lot produced. [21 CFR 114.80(a)(4) and 114.100(b)]

Mr. Anthony F. Figaretti

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This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you at the conclusion of the inspection, may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA and promptly initiating permanent corrective action. Also, federal agencies are advised of the issuance of all Warning Letters so they may take this information into account when considering the award of contracts or issuing certificates of export.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including each step that has or will be taken to correct the current violations and the timeframe within which the corrections will be completed. Corrective actions should also indicate the person responsible for effecting correction and include any supporting documentation indicating that correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the timeframe within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,

A handwritten signature in black ink, appearing to read 'L. Bowers', with a stylized flourish at the end.

Lee Bowers

Director, Baltimore District